

In re Application of: Shih *et al*
Serial No.: 09/431,519
Filed: November 1, 1999

REMARKS

The deadline for filing an Appeal Brief for this application was February 13, 2007. In place of an Appeal Brief, applicants are filing this Request for Continued Examination, with a petition for a three-month extension of time. As this paper is being filed on or before May 13, 2007, it is respectfully submitted that this paper is timely filed.

Claims 43-72 are pending in the application. Claims 43-72 stand rejected. Claims 43, 48-52, 58 and 65-70 have been amended. Claims 21-42 were previously withdrawn by the Examiner. Claim 66 has been canceled. Applicants have added new claims 73-77. Support for new claims 73-77 can be found in pending claims 51-55 as well as in the specification from page 7, line 9 to page 8, line 13 and page 10, lines 18-24. No new matter has been added with the filing of this amendment.

Applicants wish to thank Examiner Levy for the courtesy of taking their phone call on May 10, 2007 about scheduling a possible telephone interview in June 2007. Applicants hope and believe that the filing of this paper will make such an interview unnecessary, however, we would gratefully accept a date from the Examiner if such an interview is deemed necessary.

In view of the new claims and remarks below, applicants respectfully submit that the application is in condition for allowance. Accordingly, applicants request reconsideration of the application, withdrawal of the rejections of record, and issuance of Notice of Allowance.

Rejections under 35 U.S.C. §112 First paragraph.

The Examiner rejected Claims 43-72 under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

In the Final Office Action, the Examiner stated the instant invention is "Ralgro pellets constituting the immediate release formulation [of applicants' invention] and an unclaimed # of discrete particles, tablets, as a controlled release formulation." (See page 2 of Examiner's Final Office Action dated June 14, 2006). In a previous Office Action, the Examiner stated that there is no support for zeranol ONLY [for the

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immediate release portion] but rather RALGRO™, which is zeranol formulated with lactose.

In response to the rejection, applicants have amended claims 43 and 58 so that the immediate release portion of the invention is directed towards zeranol and a diluent. Support for this amendment can be found on page 7, lines 9-17 as well as originally filed claims 1-20. Further, applicants respectfully point the Examiner to page 7, lines 14-15 where it specifically states, "commercially available Ralgro™ is formulated with lactose." Support for other diluents other than lactose can be found on page 7, lines 14-15 where it states that other diluent materials include mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and the like.

Therefore, applicants respectfully request the withdrawal of these rejections under §112, first paragraph.

Amendments

Claim 43 has been further amended to include "consisting essentially" of language for both the immediate release and controlled release formulations. Additionally, the term "diluent" has been added for the controlled release formulation. Support for these amendments can be found on page 9, lines 21 to 29 of the specification.

Claims 48 and 49 have been amended to remove the term "said" found before the term zeranol.

Claims 50-52 have been amended to describe a diluent of the controlled-release formulation portion of the claimed invention. Support for these amendments can be found on page 9, lines 21 to 29 of the specification.

Claim 58 has been amended to include "consisting essentially" of language for both the immediate release and controlled release formulations. Additionally, the term "diluent" has been added for the controlled release formulation. Support for these amendments for anabolic agents like zeranol can be found on page 9, lines 21 to 29 of the specification.

Claims 65 to 70 have been amended with regard to the diluent of the immediate release and controlled release formulation. Support for these amendments can be found on page 9, lines 21 to 29 of the specification.

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Applicants respectfully submit that in view of the above response, applicants have sufficiently addressed the Examiner's rejections and that the application, as amended, is in condition for allowance.

If any additional fees, are determined to be due by this paper, the Commissioner is hereby authorized to deduct such fees from **Account No. 19-0365**.

If for any reason the Examiner believes that an interview would be helpful to resolve any remaining issues, he is invited to telephone the undersigned at the number listed below.

Respectfully submitted,



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Date: 5/11/07

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